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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,119	04/13/2007	Gary Kevin Robinson	05794.00004	1176

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FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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10/07/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary**Application No.**

10/577,119

Applicant(s)

ROBINSON ET AL.

Examiner

GINNY PORTNER

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/7/11.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 5a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,2 and 4-12 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-893)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date ____

DETAILED ACTION

Claims 1-2, 4-20 are pending; claims 13-20 are withdrawn from consideration; claims 1-2, 4-12 are under consideration.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 7, 2011 has been entered.

Objections/Rejections Withdrawn

2. **Withdrawn** The objection to claim 4 for reciting a plurality of non-peptide hydrolyases, specifically chemical compounds, such as CNBr, is herein withdrawn in light of the amendment to refer to these species as compounds capable of irreversibly hydrolyzing amide bonds in peptides and proteins.

3. **Withdrawn Claim Rejections - 35 USC § 112** Claim 4 have been amended to recite the term "compound" with reference to the limitation s"BNPS skatole," "CNBr", "formic acid", iodosobenzoic acid" and NTCB"" in dependence upon claim 1 which recites "peptide hydrolase"; the claim is no longer unclear.

1. **Specification** The amendment filed May 20, 2010 is no longer objected for minor informalities because the term "or compounds" has been removed from paragraph [0027] which defines "Peptide hydrolyases to be enzymes".

2. **Claim Objections** Claim 1 is no longer objected to because of informalities in light of the amendment of claim 1 to recite only down regulating LuxR; the claim is no longer internally inconsistent.

3. **Withdrawn**, The rejection of claims 1, 4, 5 (cell death), 6(Pseudomonas), 7(glass test tubes), 9, 11-12 under 35 U.S.C. 102(b) as being anticipated by Slaton (1958) is herein withdrawn in light of Applicant's traversal and new grounds of rejection set forth below.

4. **Withdrawn** Claims 1,2,5,6,7,9, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al WO2003/068951 or 102(e) PG-Pub 2005/0155088 (citations taken from PG-Pub for ease of pointing out citations) is herein withdrawn in light of the amended claims requiring the amide bond being cleaved to be a part of a peptide or protein.

Election/Restrictions

1. Newly amended submitted claims which recite the term "compound" are directed to an invention that is independent or distinct from the invention originally claimed for the following

reasons: The originally elected species was a peptide hydrolase enzyme and not a compound that will hydrolyze a peptide or protein amide bond.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, this species of invention which is recited in all of the amended claims is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

1. Applicant's arguments filed February 7, 2011 have been fully considered but they are not persuasive in light of new grounds of rejection set forth below.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-2, 4-5, 7-8, 9, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Carpenter et al (US Pat 5,258,304).

Carpenter et al disclose a method in which biofilm formation is inhibited (see claim 1 and 9 “trypsin”) on a surface (see title “removing microorganisms from surfaces”), the method

comprising the step of:

Treating the bacteria (Col. 21, lines 49-55) with a peptide hydrolase (trypsin (claim 9) or chymotrypsin (claim 9) capable of irreversibly hydrolyzing amide bonds in peptides and proteins (see Carpenter claims 1-3 "bacterium", claim 9, trypsin or chymotrypsin)

wherein the surface may be the surface of a contact lenses, metal, ceramics (col. 3, lines 52-54), to include surgical instrumentts, pepelines, metal containers, plasitics and composite materials (see col. 19, lines 3-14)

wherein the composition further comprises (see col. 19, lines 52-53 "combination") a detergent (see col. 22, lines 37-53) col. 20, lines 18-25), a surfactant (col. 22, lines 11-27), a biocide (anti-microbial agent (see col. 21, lines 66-67), anti-fungal (see col. 19, lines 30-3), a perfume (see col. 21, lines 64-65 "anti-odor fabric softeners"), a pH regulator (see col. 21, lines 40-42 and col. 20, lines 26-32 "Buffers"), the composition being a dispensable liquid (see col. 21, lines 22-23 "liquids, gels, pastes, solid particles such as powders and granules"; see claims 6-7).

The mechanism of action of the trypsin containing composition with respect to LuxR is not discussed nor disclosed in Carpenter et al, but the activity of the trypsin of Carpenter et al functions in the same way Applicant's trypsin composition functions, specifically to hydrolyze amide bonds in peptides and proteins of the bacteria, and therefore has the same or equivalent effect of inhibiting biofilm formation. While Carpenter et al does not discuss LuxR down regulation, Carpenter et al carries out the same or equivalent methods steps as now claimed and therefore anticipates the instantly claimed invention as now claimed.

1. Claims 1-2, 4-6, 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bjarnason (US PG-Pub 2002/0141987).

Bjarnason disclose the instantly claimed method that comprises the step of

Treating [0022-0023, 0030] bacteria [0026, 0031 bottom of paragraph “Klebsiella, Pseudomonas”] with a serine proteinase to include trypsins and chymotrypsin [0013](see abstract)]

to treat or prevent infection [0052], infection being associated with biofilm formation for Pseudomonas or Klebsiella (page 3, [0024, 0026 and 0031], the treating being by administering a dispensible liquid with an aqueous carrier, or a composition with non-aqueous carrier (see [0048] that may be in the form of a spray (aerosol[0048], gel or tablet)

which is pH regulated (see [0048] bottom half of paragraph) and

may comprise a surfactant (excipient, lines 20-35 “glycerol”). The mechanism of action of the trypsins and chymotrypsin containing composition with respect to LuxR is not discussed nor disclosed in Bjarnason, but the activity of the trypsins and chymotrypsin functions in the same way Applicant’s trypsins and chymotrypsin composition functions, specifically to hydrolyze amide bonds in peptides and proteins of the bacteria, and therefore has the same or equivalent effect of inhibiting biofilm formation. While Bjarnason does not discuss LuxR down regulation, Bjarnason carries out the same or equivalent methods steps as now claimed and therefore anticipates the instantly claimed invention as now claimed.

Conclusion

This is a non-final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
September 23, 2011

/Mark Navarro/
Primary Examiner, Art Unit 1645

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